

**Health Information Technology Standards Committee
Final
Summary of the September 21, 2010, Meeting**

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 17th meeting of the Health Information Technology Standards Committee (HITSC). She reminded attendees that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments. Following her opening remarks, she conducted roll call and turned the meeting over to HITSC Chair Jonathan Perlin.

2. Opening Comments and Review of the Agenda

Jonathan Perlin indicated that at this meeting, Committee members would be considering the implications of the standards to support Stages two and three in the evolution of meaningful use. The work of the HITSC relates to an emerging internal coherence that is increasingly available for the operation of electronic health records (EHRs). He reviewed the day's agenda, and introduced HITSC Co-Chair John Halamka.

John Halamka indicated that he was looking forward to the Committee's discussion on intellectual property issues. He noted that the Certification Commission for Healthcare Information Technology (CCHIT) had a 500-person conference call yesterday on introducing the certification process in detail. Based on some of the questions that have been posed, the Implementation Workgroup has a significant amount of work to do in helping to ensure that those in the trenches are able to get their work done.

Action Item #1: Minutes from the last HITSC meeting, held on August 30, 2010, were approved by consensus.

3. Vocabulary Task Force Briefing on Hearing

Vocabulary Task Force Co-Chair Betsy Humphreys commented on the widely held expectation that once there was a rule in place indicating certain clinical terminologies must be used, this would lead to a significant reaction, and it did. She reported that there has been an enormous increase in the number of people per month who are licensing the Unified Medical Language System (UMLS), which is necessary to get SNOMED CT and certain parts of RxNorm, as well as the number people who are using the National Library of Medicine's Application Programming Interfaces (APIs) to get various vocabularies. The first 6 months of this year experienced a higher volume than did all of 2009.

Vocabulary Task Force Co-Chair Jamie Ferguson reminded the group that one of the central concepts that arose from the Task Force's previous set of hearings and discussions was the need for one-stop-shopping, to make it easy for implementers to obtain the required vocabulary components. These components include content, cross maps, value sets, and derivative works. The recent hearing was convened to determine what the requirements should be for this one stop shop. Overarching questions guiding these discussions included: What does one-stop shopping mean from the different stakeholder perspectives? What is most urgent, and what must happen first?

The hearing included four panels with a total of two dozen panelists representing a mix of public and private-sector participants. Jamie Ferguson discussed some of the major themes, with a focus on intellectual property issues.

The Task Force heard from panelists that there is a desire to have simplicity and harmony with regard to vocabularies, taxonomies, and mappings. Clarity of requirements and clarity of guidance was emphasized more so than simplicity. The government must be clear about what is required of those who are applying for meaningful use funds and implementing these technologies. A related theme is the overriding desire for stability and predictability in terms of those requirements. People must know what the requirements are and what the roadmap is for the future.

There was also discussion about what simplicity means for different stakeholders, and the need for having exception mechanisms. It was noted that there should be a process to prioritize what is needed most immediately. Several cross-maps were mentioned multiple times, with SNOMED CT to the ICD-9 CM and the ICD-10 CM being the most frequently mentioned. RxNorm was also mentioned frequently in terms of cross-map requirements.

Another part of the overall plan is for information about value sets to be readily disseminated and easily downloaded from the one-stop-shop. However, information about value sets can be very complex, and not everything is needed up front. At the same time, more than just a list of codes is needed: there also must be a context, a description of why the value set exists and what its intended purpose and limitations are.

Jamie Ferguson noted the importance of immediately making a U.S. version of SNOMED CT, with U.S.-specific extensions readily available. He paused his presentation to take questions from the Committee. That discussion included the following highlights:

- Jamie Ferguson noted that in its previous recommendations to the National Coordinator, the Task Force suggested that there should be a single federal office or agency in charge of this coordination, handled out of ONC. This has not happened yet.
- Stan Huff commented that one can think of the national work that needs to be done as essentially a librarian function, in which the work that has been done by others is indexed and made available. This effort is not an attempt to create a new body of experts, but rather to bring together the knowledge and allow the processes that are already in place to establish the content.

- Doug Fridsma noted that some of the problems that they are trying to solve are complex. With complex problems, simple solutions sometimes are mismatches. He suggested that the Committee focus on making things clear, rather than making them simple.
- Dixie Baker asked if The Vocabulary Task Force expects concept versioning to be maintained as stable across value sets. She also asked if the Task Force anticipates replacing concept extensions with code set concepts if one is released that is equivalent with an equivalent code that is released. Betsy Humphreys commented that the group will have to see how this evolves. In the near term, it seems impossible to imagine that all of this would be happening simultaneously.
- Wes Rishel noted that creating simplicity feeds back into creating clarity. As the Task Force tries to make it simple and leave decisions to the last implementer, this tends to leave things undecided. He pointed to the need for a feedback process that goes all the way through and back.

Jamie Ferguson then resumed his summary of the Vocabulary Task Force hearing. The group consistently heard that version management is critical to implementers. The possibility of expiration dates on different content sets was discussed, to essentially force updates to maintain currency in version management schemes.

Technology infrastructure was another theme. The hearing focused on system performance characteristics, availability, up-time, and appropriate security around the technology that was used for the one-stop shop. Some panelists suggested using particular aspects of cloud technology and some distributed solutions. The requirements were to have good and published up time, and to have appropriate system performance, which may involve load balancing or other types of solutions. Whatever the solutions are, they must create a stable, available system.

At the hearing, there also was a discussion about what was termed off-label use of the value sets. In some cases, certain uses of value sets for activities other than their intended use can cause serious problems. In other cases, there may be no problems. Information about permissible off-label uses of the value sets could be helpful.

Intellectual property issues can be a significant barrier to implementation. This extends beyond proprietary medication or procedure vocabularies to include extensions, derivative work such as the cross-maps of proprietary intellectual property, and value sets that contain the intellectual property. At the hearing, this issue also was raised with regard to the use of HL-7 as well as X12 messaging standards that contain particular value sets that have intellectual property. The focus of the hearing was on the vocabularies and not on the messaging or infrastructure standards, but the same vocabulary issues in terms of intellectual property, licensing, and restrictions were raised in the context of the messaging standards as well.

At the hearing there was agreement that the intellectual property issue represents a major problem—the solutions proposed varied widely. On one side of the spectrum of potential solutions, some suggested simply making monopolies illegal and disallowing monopolies for any

code sets that charge fees. On the opposite side, others suggested that the government should pay national licensing fees, which would essentially make it free to everyone who implements this intellectual property in the United States.

The Canadian intellectual property model was discussed. Canada provides a national license, with providers paying a user fee essentially for the use of the intellectual property that defrays a part of that licensing cost.

It was suggested at the hearing that some party other than the providers who are implementing EHR technology for meaningful use should be administering the intellectual property, processing the payments, and potentially even negotiating the license fees. Jamie Ferguson asked Committee members to comment on the concept of centralized administration of intellectual property.

In discussion, the following points were made:

- John Halamka indicated that the idea of some entity administering intellectual property issues was an extremely practical proposal. Betsy Humphreys noted that even the cost of paying for an HL-7 standard is more than many county public health departments in the United States can afford. A very simple system must be devised to track who has paid and who has not. This is a very attractive and probably very possible solution, but there are many details to be worked through.
- Jamie Ferguson pointed out that the scope of this recommendation is for meaningful use. Meaningful use has a known list of eligible professionals and hospitals and other specific types of organizations that would serve as the licensees, so there is a very specific list of who would be covered.
- Jim Walker commented that even granted that limited scope—and particularly in view of the fact that the scope is going to have to expand dramatically to meet the country's needs—it would be worth conducting a very careful economic analysis. He believes that analysis would show that the cost of accounting for this was greater than the cost of the government licensing the various rights and providing them to anyone who wants to use them.

4. Implementation Workgroup Update

Implementation Workgroup Chair Judy Murphy presented the Workgroup's new, expanded list of members and its broad charge. At its September 15, 2010, meeting, the group discussed its potential future activities. These include recommending that the ONC create a publicly accessible online report/dashboard to track implementation progress (e.g., of meaningful use qualification, regional extension centers, state programs, Beacon Communities, and the Nationwide Health Information Network [NHIN]). It will be important to carefully track progress to avoid duplicative efforts. Specifically for meaningful use, the Workgroup suggests providing access to lists of: (1) vendors who completed certification, (2) providers/hospitals who have registered with the Centers for Medicare and Medicaid Services (CMS), (3) providers/hospitals who have attested to meaningful use with CMS, and (4) providers/hospitals

who have successfully achieved meaningful use qualification and will be receiving incentive payments. The overall goal is to provide situational awareness and transparency, as well as access to potential resources.

Workgroup Co-Chair Liz Johnson noted that said that the Workgroup has heard that when some users visit the CMS and the ONC Web sites, they fall into a circuit, moving from link to link and to large documents that are almost uninterpretable by the public. There is a call for simplification.

Judy Murphy continued with the list of potential Workgroup activities, noting that some feedback is needed because the Workgroup cannot address all of these issues, although they realize they must partner with ONC to tackle the work. Additional potential activities include the following:

- Provide feedback to the HITSC and HIT Policy Committee (HITPC) recommendations.
- Advertise and encourage the use of existing resources such as the Health IT Buzz Blog, Federal Advisory Committee Blog, Health IT Journey - Stories from the Road, ONC FAQs, and CMS FAQs.
- Evaluate and consider the use of social networking tools to connect people and learn from each others' implementation efforts.
- Provide clarity on meaningful use specifications and resolve any confusion on available resources (e.g., create a ~~playbook~~" for meaningful use, provide guidance on NHIN and NHIN Direct; and help providers/hospitals determine how to bridge efforts in terms of meaningful use performance, quality measures, and NHIN).
- Clarify consumer expectations of EHR vendor certification (i.e., what can they actually expect from a ~~certified~~ EHR product"?).
- Consider a home for the questions that the National Institute of Standards and Technology (NIST) is not able to answer and a place to publish —lessons ~~learned~~."
- Ascertain if it would make sense to create a version of the NIST test scenarios for consumers to use in evaluating their implementation/adoption of the EHR.
- Determine what drives the Workgroup's agenda (e.g., input from others, feedback from HITPC and HITSC policies and programs).

Liz Johnson commented on the need for the Implementation Workgroup to be responsive in a proactive and timely manner to get the public the information it needs.

The Committee had a discussion, which included the following highlights:

- John Halamka agreed about the importance of communication to the public..

- Walter Suarez commented that it is difficult to disagree with any of the topics that were listed as potential Workgroup activities. The challenge is to define the scope of these activities. The various activities listed include education, outreach, monitoring, and evaluation. He suggested that the Workgroup's charter is to examine best practices for implementation around the country and identifying issues of implementation. The primary interest is on the implementation of meaningful use and health information exchanges (HIEs) from the standpoint of the standards, how the implementation of those standards was occurring, and to try to identify best practices to highlight pathways for others to follow.
- Dixie Baker suggested that organizations will need more guidance in how to conduct a risk assessment and how to configure the security functions that are available in their EHR so that they will counter the risks that have been identified. NIST has some excellent documents on security, but the small practices in particular will need something very specific.
- David McCallie asked about who the primary consumers of this information will be (vendors who are implementing the systems, customers of those vendors, or both?). The way that the information is structured will differ based on the primary audience. Judy Murphy indicated that the intended audience is both vendors and customers, which could lead to an uncoordinated and therefore unsuccessful effort. Liz Johnson noted that if the Workgroup has to focus on one or the other, the answer would be the end user. Judy Murphy noted that the loudest cry for help is coming from the smaller providers. If the Workgroup can take the lessons of the larger organizations and translate them into assistance for the smaller doctor's office, then the work will be very meaningful.
- In response to a comment by Wes Rishel, Judy Murphy pointed to the need in differentiating whether the proposed Web site will serve as a place for posting anecdotes or personal experiences, compared to a site containing official comments from sources like ONC.

5. Standards and Interoperability Framework

Doug Fridsma updated the Committee on the Standards and Interoperability Framework Kickoff Meeting that was held on the day before this meeting and discussed lessons learned in two of the initiatives that have used the Standards and Interoperability Framework at this point: the NHIN Direct project, and some administrative simplification work on Section 1561 of the Healthcare Reform Bill.

Three guiding principles have been identified within the Office of Interoperability and Standards: (1) promotion of a sustainable ecosystem that drives increased interoperability and standards adoption; (2) creation of a collaborative, coordinated, and incremental standards process that is led by the industry in solving real-world problems, and (3) the leveraging of government as a platform, so that the government is not in the business of creating new standards, but is instead providing tools, coordination, and harmonization to support those trying to develop solutions. Doug Fridsma listed all of the contractors that have been chosen for various contracts targeting aspects of the meaningful use work.

With regard to the National Information Exchange Model (NIEM) process, he explained that the information exchange package document (IEPD) is a technical collection of artifacts that

describes the construct and the content of an information exchange. It is the package that helps define implementation details and provides business, functional, and technical details of how an exchange would occur. The IEPD creates a core set of artifacts that work together and uses prescribed formats and structures for consistency. It is meant to be shared and reused. The IEPD is modular in its construct so that different pieces can be used in different types of exchange. It does not contain design specifications necessarily—it contains design specifications for information exchange, but it may not include all of the supplementary information such as implementation decisions. Work is ongoing with the team that has coordinated NIEM in the past to examine the possibility of extending some of the items that are found in the information exchange package in support of this work.

ONC is working to develop a common core that is focused on HIE and calling it NIEM Health to differentiate it from some of the other NIEM concepts. The goal is to focus on issues of health first. ONC recognizes that with the Department of Health and Human Services (DHHS), there is both the health side and the human services side. The human services group has already begun developing IEPDs that use the NIEM core. This group is going to focus on the health aspect, and they will at some point need to determine how best to bridge these. They are addressing a number of challenges. They must identify where there are gaps, duplications, and overlaps in existing exchange requirements and address them. They will also need to determine how to leverage and manage the existing repositories for vocabularies. They are working on computable and usable implementation specifications, and they are addressing some of the IEPD's shortcomings—altering its structure and content so as to include transport and behavioral activities, as well as the security aspects of exchange.

Doug Fridsma explained that nothing in this approach is intended to be top down. He suggested that Committee members think about this as bottom-up standards development within a top-down coordinating mechanism, so that if the next project has an overlap with some of the NHIN Direct specifications, there is a way to work through it without using a top-down perspective.

In discussion, the following points were made:

- In response to a question about how they will synthesize input from all of the various participants, Doug Fridsma commented that this is a significant issue and one that he would like Committee guidance on. There are a few possible approaches. One is to try to take all of the existing things and backfill them into the infrastructure that is already in place and create a common approach from a technical perspective. More broadly, they must think about how to establish priorities for the work, given that there will probably always be more to do than can be taken on.
- Doug Fridsma explained that the output of this project is implementation specifications tested by reference implementations. In some sense, it is also an effort to address the one-stop-shop concept that was articulated by the Vocabulary Workgroup, not just with regard to vocabulary, but also with respect to what the data standards might be, the metadata that would be required, etc. The intention is not to build specific solutions per se, but to help coordinate how those things might get constructed so that there is reusability and it can be leveraged in other ways. He could not speculate on whether NIEM was going to be a strong

suggestion, a recommendation, or a mandate for states and private entities. In the short term, the goal is to provide support for implementation specifications that are currently part of meaningful use Stage 1. He hopes that as the approach matures, Stage 2 and Stage 3 implementation specifications can also be part of this process.

- Wes Rishel said that he thinks this process somehow needs to become more public.
- Jamie Ferguson asked Doug Fridsma to elaborate on the relationship of existing adopted standards to the S&I framework. Doug Fridsma replied that the issue had not yet been dealt with, but he would take it back for consideration.
- David McCallie commented that as much as he appreciates the need for model-driven, top-down thinking, somehow in the process the bottom-up, real-world implementation experience needs to filter in.
- Dixie Baker noted that NIEM only addresses data content. Transaction behavior and security provisions are necessary for HIE. She asked why those two items were excluded and whether it was due to inherent limitations to the NIEM process. She also asked how those needs were handled by DHHS and the Department of Justice. Doug Fridsma indicated that he would bring those questions back to the NIEM team.
- Chris Chute emphasized the need to be mindful of the advantages associated with coherent coordination with an artifact that can be publicly viewed as an overarching model for these bottom-up activities. He agreed with the prevailing wisdom that creating an excruciatingly detailed, top-down artifact is not beneficial or consistent with timelines and expectations. However, it is plausible to dynamically create the “big picture” and keep it in mind a maintained artifact so that people can see the context of where these components fit and how they operate.
- Walter Suarez asked about the process for engagement. What is the official, formal process to being able to be engaged or participate? Are there going to be announcements that will invite participants to join this team? Doug Fridsma explained that those discussions have not taken place yet, noting that the use case contract was just awarded. He agreed that the ability to engage the community and create interest around this work is important.
- Cris Ross urged thorough communication regarding the connection of policy and standards to this work. He also said that he keeps hearing that NHIN Direct is wonderful, but he does not understand exactly how it maps to meaningful use. Connecting these is one of the issues that the Implementation Workgroup will address.
- Walter Suarez reminded the group that an important priority is HIE messages. In the ongoing state efforts to develop HIE, one of the very specific and most immediate challenges is determining what the messages are that will be exchanged within the HIE. He expressed hope that this would be considered part of the priority setting within this framework.

- Dixie Baker commented that the general framework that will be developed for addressing issues in vocabulary management should also apply to the lifecycle management of implementation specification. She encouraged these two efforts to come together in addressing these issues so that there is one approach for both.
- Linda Fischetti said that empowering consumers with their own information is one initiative that should be tagged as important.

6. Setting Priorities

John Derr of Golden Living reminded the group about that nursing homes and home care needs to be considered when they work on pilots for meaningful use Stages 2 and 3.

Doug Fridsma noted that what he has heard from various testimonies suggests that there are some barriers to reaching adoption—some of them around the intellectual property issue, some of them around the value sets that need to be articulated. There are a few models that could be used for setting priorities. One would be to identify a broad range of activities and build foundations across all of them. They must then define what that foundation would be and what the important elements might be. This is different than taking one or two key problems and trying to solve them. NHIN Direct took a small problem and went all the way from articulating the use case, developing the specifications, testing the reference implementations, and making sure that the whole enterprise worked. Those are two different ways of attacking the work ahead for Stages 2 and 3.

Committee discussion included the following highlights:

- Jonathan Perlin explained that as an end user, the degree to which Stage 2 allows one to “thread the needle” for Stage 3 will be the degree to which it is representative of the needs of the broader constituency for success.
- Chris Chute commented that one of the lessons of the Healthcare Information Technology Standards Panel (HITSP) was that modularity had significant advantage and significant generalizable value. His concern is that if the Committee focuses myopically on Stages 2 and 3 of meaningful use, they are at risk of doing the same thing in a way that would not be generalizable or coherent. It may be advantageous to consider standard specification in the context of these modules or components where they are originally initiated or brought forth to fulfill a particular use case. However, the goal has to be that they are cast as specific generalizable components that can be used, ideally in multiple places.
- Doug Fridsma explained that in software engineering, often an effective, lean software package is developed to meet a particular purpose, but that “feature creep” can occur, whereby the software becomes bloated with add-ons and inefficient. In these cases, the software engineers go back and re-factor the software, creating more modular and better ways of carrying out the tasks. In some sense, what happened in the last stages of HITSP was a semantic re-factoring of the standards that it had to try to create those modules.

- David McCallie commented that their timing may not allow for any kind of assessment of the decisions that were made in Stage 1 before they recommend Stage 2. He noted that a number of important experiments have been conducted in the work to date, and efforts should be made to see what can be learned from these experiments before continuing down the same track. For example, both CCR and CCD were endorsed at a time when there are several new proposals that simplify both of those to slimmer, more focused XML snippets (e.g., hData or Green CDA). NHIN Direct and NHIN Exchange do not theoretically overlap, but will lead to some learning about the best way to share information. He asked if there would be time for this kind of assessment, acknowledging that the timetable continues to be extremely fast.
- Doug Fridsma noted that one way to quickly know what works and what does not work is to drive it all the way down to actually put it in practice. If they spend a lot of time in the abstract, developing large use cases and never quite getting to the level of implementing whatever the framework or the use case might be, they will never know if they have actually succeeded.
- Doug Fridsma asked about what the missing piece was that would provide the biggest “bang for the buck” and that can be accomplished in a fairly constrained period of time. That should be one of the top priority use cases because it would focus the group on what providers and patients need. There are standards around prescribing, and around the exchange of clinical information. What is the next piece that would be of high value?
- Chris Chute suggested considering a portfolio of micro-foci as well as some larger areas of focus. The Committee might not be able to anticipate what could happen in a few weeks, when a whole set of practices may run into a common problem. If there was a quick response team available to solve the problem—not in 2 months but in closer to 2 weeks—that would be helpful.
- Carol Diamond cautioned that the discussion around prioritization and standards sounded somewhat academic. If the group is successful in this effort, government and the process that is being run at ONC will not be the bottleneck and competing priorities will not need to be triaged. She suggested that the Committee go back to some of the early principles on this, which are to make sure that the standards that are being used separate transport from messaging from content, and sticking with some of those first principles enables more to be done than viewing this effort as a single thread.
- Wes Rishel suggested that the committee may want to have a formal discussion in terms of what it thinks might be measures of success—to create a position whereby it can trade off different schools of thought and advice on how this should proceed.
- Jamie Ferguson summarized some main points of the discussion. Doug Fridsma suggested building out some crosscutting foundational elements first, or, alternatively, picking one or two use cases and approaching it more as a “vertical slice.” To a large extent, the Committee has been discussing how to combine those two to achieve the most value. There was discussion about focusing on Stage 3 as a goal, and then backing into Stage 2. There has been a significant amount of discussion on how to integrate existing building blocks; this

should be done in parallel with developing the new content and specifications for Stage 2. Committee members also discussed the scope of a use case. There is a general agreement that the scope of use cases should be small so that modular solutions and specifications that solve for those are highly generalizable and can be re-assembled for more value.

7. Public Comment

Tom Bizarro spoke from First DataBank, which provides vocabularies for use within health information systems. The group supports the development of national standard vocabularies to promote interoperability in exchange of health information. The vocabularies must be timely, comprehensive, and accurate. They need to be well-maintained with support that addresses the needs of the user and deals with gaps and errors in the content. Also, there must be a realization that these vocabularies will be integrated in patient care applications used at the point of care and will impact the quality of care that the patient receives.

Robin Raiford from Allscripts encouraged Doug Fridsma to look at IS 107 and the EHR-centric piece that came out of HITSP. With respect to long-term, post-acute care, she said that one of the most interesting things that came out of a recent summit was the significant advantage that long-term, post-acute care has. One of the most concerning things she heard at last week's HITPC meeting was that vendors may have 18 months' advance notice of the concept, but they would not know the details until much later. Code cannot be written without detail.

Shelly Spiro spoke from Pharmacy EHIT Collaborative, which is made up of nine of the National Pharmacist's Associations. The Collaborative has created a pharmacist EHR. As pharmacists, they provide many services outside of just the transfer of prescription information. In many cases pharmacists are the single caregiver in many locations in the rural and community settings. It is important to remember that the role the pharmacists are playing is critical as it relates to medication management and medication reconciliation.

SUMMARY OF ACTION ITEMS

Action Item #1: Minutes from the last HITSC meeting, held on August 30, 2010, were approved by consensus.